

Remarks

Claims 6-10, 33, 36, and 37 are pending in the present application.

Claims 6-10, 33, 36, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claim 33 has been amended to clarify the claim by adding a subscript to the term CI. Claim 9 is amended to correct an antecedent basis issue. No new matter is added by virtue of the amendments. The claims as amended are believed to be sufficiently definite for purposes of 35 U.S.C. 112, second paragraph. Claims 6-10, 36 and 37 depend from claim 33. As such, reconsideration of the rejection, leading to its withdrawal and allowance of the claims is respectfully requested.

Claims 6-10, 33, 36, and 37 are rejected under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, the rejection proffers that the specification does not provide any guidance for determining the values (variables) necessary for using the equation (8) for calculating G_p . The rejection is respectfully traversed.

As will be discussed below, claim 33 is amended to recite a unit for measuring the actual glucose concentration (G_a) in a patient's bodily fluid. The Examiner's statement that the specification is enabled for one of skill in the art to practice the claimed invention as directed to "measuring" the actual glucose concentration is acknowledged. The empirical weight factor D, is not necessary for measuring the actual glucose concentration (G_a). As such, (G_a) is not determined by the empirical weight factor D, as proffered by the rejection. Claim 33 as amended is believed to be enabled as directed to G_a .

The rejection further proffers that G_a as directed to the actual glucose concentration is determined by the factor E. As discussed above, is amended to recite a unit for measuring the actual glucose concentration (G_a) in a patient's bodily fluid. The Examiner's statement that the specification is enabled for one of skill in the art to practice the claimed invention as directed to "measuring" the actual glucose concentration is acknowledged. As such, the factor E, is not necessary for measuring the actual glucose concentration (G_a) and claim 33 is believed to be enabled as directed to G_a .

The rejection proffers that X, E, and SE are not enabled with regard to claim 33. That rejection is respectfully traversed. It is submitted that neither X, E, nor SE are necessary for the system of claim 33, as amended. Specifically, while X, E, and SE may be used, none are necessary for the determination of G_p . The specification teaches at page 3 lines 18-20 and page 5 lines 17-28 that the extrapolation of the future glucose concentration (G_p) includes

(a) the determination of the portion of insulin dose that will become effective in the interval between measurement and the extrapolated point in time, and

(b) the determination of the portion of the carbohydrates consumed that takes effect in this time interval.

Neither of these two parameters necessitates the use of the factors X, E, and/or SE.

It is submitted that one skilled in the art would readily be able to determine (a) the portion of an insulin dose that will become effective in a pre-determined time interval. In that regard, the Examiner's attention is directed to the working example of Figure 1 and the text of the specification at page 6, beginning at line 9. The specification teaches that the portion of insulin that takes effect in a period between measurement and the projected point in time can be calculated by first determining how much time has passed since administration of the insulin and the current point in time. "The portion of insulin that is effected in the projected period can be determined in integrating the curve between t_a and t_p and multiplying this value by the number of insulin units administered." Page 6 lines 13-16. As such neither X, E, nor SE are necessary for the determination of the portion of insulin dose that will become effective in the interval between measurement and the extrapolated point in time.

Further, it is submitted that one skilled in the art would readily be able to determine (b) the portion of the carbohydrates consumed that takes effect in this time interval. In that regard, the Examiner's attention is directed to the working example of Figure 3 and the text of the specification beginning at 9 line 7. The specification teaches that "the effectiveness of the carbohydrates in the organism is given by the glucose "flooding". Page 9 lines 7-8. Next, the Examiner's attention is directed to Figure 3, which is a model showing the moment of carbohydrate consumption indicated as t_e , and

the time of measurement indicated as t_a . The time to which the glucose concentration should be projected is indicated as t_p . "The portion of effective carbohydrates is therefore shown as the area described as A_2-A_1 ." Page 10 lines 4-5. Using the text of the specification and the example of Figure 3, neither X, E, nor SE are necessary for the determination of the portion of insulin dose that will become effective in the interval between measurement and the extrapolated point in time.

As such, the factors X, E, and SE are not necessary for determining (G_p) as set forth by claim 33. Accordingly, claim 33 is believed to be enabled in accordance with 35 U.S.C. 112, first paragraph. Claims 6-10, 36 and 37 depend from amended claim 33. As such, reconsideration of the rejection leading to its withdrawal is respectfully requested.

Claims 6-10, 33, 36, and 37 are rejected under 35 U.S.C. 112, first paragraph because the specification, while being only enabling for "measuring" the actual glucose concentration, does not reasonably provide enablement for "determining" the actual glucose concentration using any other theoretical determination method. The rejection is respectfully traversed in light of the amendment to claim 33. The Examiner's statement that the specification is enabling for "measuring" the actual glucose concentration is acknowledged. Claim 33 has been amended to recite the step of measuring the actual glucose concentration.

Accordingly, claim 33 is believed to be enabled in accordance with 35 U.S.C. 112, first paragraph. Claims 6-10, 36 and 37 depend from amended claim 33. As such, reconsideration of the rejection leading to its withdrawal is respectfully requested.

The claims are believed to be in condition for allowance, and allowance of the application is respectfully requested. It is requested that this paper be considered a Petition for Extension of time sufficient to effect a timely response, and that all fees due be charged to Deposit Account Number 50-0877 with reference to (RDID 0006 US).

Respectfully submitted,
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